A Phase 2 Study of the Safety of Repeat Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa

Grant Award Details

A Phase 2 Study of the Safety of Repeat Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-11472

Investigator:

Name:	Henry Klassen
Institution:	jCyte, Inc
Type:	PI

Disease Focus: Retinitis Pigmentosa, Vision Loss

Cell Line Generation: Adult Stem Cell

Award Value: $6,608,592

Status: Pre-Active

Grant Application Details

Application Title: A Phase 2 Study of the Safety of Repeat Intravitreal Injection of Human Retinal Progenitor Cells (jCell) in Adult Subjects with Retinitis Pigmentosa

Public Abstract:

Therapeutic Candidate or Device

Allogeneic human retinal progenitor cells (hRPC)

Indication

Retinitis Pigmentosa (RP)

Therapeutic Mechanism

The cells are intended to remain suspended in the vitreous cavity of the eye and exert a beneficial neurotrophic effect on the degenerating retina.

Unmet Medical Need

RP is an incurable orphan disease. There are no treatments currently available other than a retinal chip for very end stage patients. To date, there is nothing that will restore sight or slow the progression of vision loss in RP. Achieving any measurable benefits would be groundbreaking.

Project Objective

CMC readiness & re-dosing

Major Proposed Activities

- Perform critical path manufacturing activities and conduct an in vitro comparability study of clinical versus commercial processes
- Validate endpoints to ensure that changes in patients' vision function and functional vision are captured by appropriate and meaningful endpoints
- Assess the safety of a repeated injection of jCell in proposed Phase 2 study

Statement of Benefit to California:

RP is a relentless blinding disease with no current treatment. There are an estimated 10,000 patients with RP in California and all are either visually disabled already or expected to become so in time. Most or all these patients will need to receive healthcare benefits, special living assistance, and will also suffer from decreased economic functionality. Treatment for RP would be a medical breakthrough that may lead to treatment for other currently incurable blinding diseases.
